REMARKS

In view of the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow claims 52, 79-81, 83-91 and 93-94 the only claims pending and currently under examination in this application.

FORMAL MATTERS:

Claims 52, 79-81, 83-91 and 93-94 are pending after entry of the amendments set forth herein. Please cancel claims 82 and 92 without prejudice or disclaimer. Claims 52, 79, 83, 84, 90 and 91 are currently amended. Support for these amendments is found in the claims as filed, and in the specification at least at paragraph [0012]. The Applicants assert that these amendments add no new matter and their entry is respectfully requested.

AMENDMENTS TO THE SPECIFICATION:

The Examiner has objected to the specification as being informal to the patent applications listed in paragraph [0001] and [0099] of the specification. The Applicants have corrected these informalities and request this objection be withdrawn.

THE REJECTION UNDER §112, FIRST PARAGRAPH

The Examiner has rejected claims 52 and 79-94 under 35 U.S.C. §112 first paragraph, as allegedly not fulfilling the written description requirement. The Applicants respectfully traverse the rejection.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 U.S.P.Q.2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991).

The Applicants assert that the specification discloses that nucleic acids can have variants and how to determine the identity between the variants in paragraphs [0062]-[0071]. The Applicants have also disclosed the claimed nucleic acid sequence (SEQ ID NO:41). Based on this disclosure and the claims as currently amended, the Applicants submit that one of skill in the art would find that the Applicants were in possession of the claimed invention. As such, the Applicants respectfully request the withdrawal of the rejection of claims 52, 79-81, 83-91 and 93-94 under 35 U.S.C. §112, first paragraph.

THE REJECTION UNDER §112, FIRST PARAGRAPH

The Examiner has rejected claims 52 and 79-94 under 35 U.S.C. §112 first paragraph, as allegedly not being enabled by the specification and refers to the *Wands* factors. The Applicants respectfully traverse the rejection.

With respect to enablement, courts have held that: "[t]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 8 USPQ 2d 1217, 1233 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989). See also *Genentech, Inc. v. Novo Nordisk*, 42 USPQ 2d 1001 (Fed. Cir. 1997), *cert. denied*, 522 U.S. 963 (1997); *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 18 USPQ 2d 1001 (Fed. Cir. 1991).

The Applicants claims are directed to methods of diagnosing kidney cancer by examining a specific gene. The specification discloses several methodologies with which to determine differential expression, for example, paragraphs [0159]-[0166] and Examples 2, 3, 5 and 9. Given the disclosure in the specification and the claims as currently amended, the Applicants submit that one of skill in the art could make and use the claimed invention without undue experimentation. Therefore, the Applicants respectfully request withdrawal of the rejection of claims 52, 79-81, 83-91 and 93-94 under 35 U.S.C. §112, first paragraph.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at (510) 923-2438.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-4409.

Respectfully submitted,

David A. Carpenter

Reg. No. 45,945

Attorney for Applicants

Customer No. 75074

May 4, 2010 Novartis Vaccines and Diagnostics, Inc. Intellectual Property P.O. Box 8097 Emeryville, California 94662-8097 (510) 923-3949 (510) 655-3542 (fax)

12